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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,765	11/24/2003	James Martucci	EIS-5799 DIV.1	4921
29200 7590 01/09/2008 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER MORGAN, ROBERT W	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 01/09/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,765	Applicant(s) MARTUCCI ET AL.	
	Examiner Robert W. Morgan	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/07 has been entered.

Notice to Applicant

2. In the amendment filed 12/21/07, the following has occurred: Claims 1, 3-4 and 6 have been amended and claim 2 has been canceled. Claims 1 and 3-6 are presented for examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,671,563 to Engelson et al.

As per claim 1, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19);

(e) the handheld computing device reading the patient data from the second label is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19);

(f) the handheld computing device comparing the prescribed medication data to the patient data and confirming a match between the prescribed medication data and the patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19); and

(g) the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Engelson et al.

also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

As per claim 3, Engelson et al. teaches the claimed step of the medication delivery device performing periodic checks of the operating parameters of the medication delivery device against the medication delivery instruction downloaded from the handheld computing device to ensure the operating parameters are within the ranges set by the medication delivery instruction after starting the delivery of the medication. This feature is met by the medical administrative management module (110, Fig. 3) that automatically records the start time of the infusion, queries the pump periodically throughout the infusion and maintains a continuous log of the infusion and the volume infused in a patient MAR (see: column 8, lines 41-47).

As per claim 4, Engelson et al. teaches the claimed the first label is encoded with the prescribed medication data and the instruction of delivering the medication derived from a print stream generated from a pharmacy information system. This limitation is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21).

As per claim 5, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19);

(e) the handheld computing device reading the patient data from the second label is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19);

(f) the handheld computing device comparing the prescribed medication data to the patient data and confirming a match between the prescribed medication data and the patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19); and

(g) the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Engelson et al. also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14,

lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

As per claim 6, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) identifying medication data contained in a first label on a medication container containing a prescribed medication, the first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) identifying patient data contained in a second label on a tag adapted to be worn by a patient, the second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) comparing the medication data to the patient data by a handheld computing device wherein the handheld computing device is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19):

means for reading the prescribed medication data and medication delivery instruction from the first label is met by barcodes (182, Fig. 5) and (175, Fig. 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24); and means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device confirming the data and communicating and downloading the instruction of delivering the medication to a medication delivery device is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Engelson et al. also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

Response to Arguments

5. Applicant's arguments filed 12/21/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 12/21/07.

(A) At pages 6-8 of the 12/21/07 response, Applicants argues in substance that Engelson does not disclose a handheld computing device reading a medication delivery instruction from a

first label and communicating and downloading the medication delivery instruction to a medication delivery device. The Examiner respectfully submits the Engelson et al. reference teaches a care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Moreover, Engelson et al. teaches that the care management system can automatically download medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit. Additionally, Engelson et al. teaches that the infusion pump can be manually configured by the physician, nurse or technician using a touch screen device, mouse or other devices connected to the bedside CPU (80, Fig. 2) (see: column 14, lines 24-36). The Examiner considers the other devices connected to the bedside CPU (handheld device) such as a bar code reader, as used to read the medication delivery instruction from a first label and then communicated to the infusion pump.

Conclusion

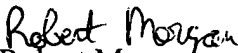
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

Application/Control Number:
10/720,765
Art Unit: 3626

Page 11

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Robert Morgan
Primary Examiner
Art Unit 3626